



**CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
PARENT / GUARDIAN AND ASSENT FOR 12 – 17 YEARS OLD**

Sponsor / Study Title: Lupin Research Inc./ “A Multi-Center, Open-Label Study to Evaluate the Safety of a Single Oral Dose of Solosec™ (secnidazole) 2g Oral Granules for the Treatment of Adolescent Girls with Bacterial Vaginosis”

Protocol Number: SYM-1219-401

Principal Investigator: «PiFullName»
(Study Doctor)

Telephone: «IcfPhoneNumber»

Additional Contact(s): «AdditionalStaffMemberContacts»
(Study Staff)

Address: «PiLocations»

Child Participant’s Printed Name: _____

Please note: If you are reading this document to decide whether your child may participate in this study, the terms “you” and “your” refer to your child.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor and/or the study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date. You cannot take part in this research study until you sign and date this form. You will be given a signed and dated copy of this informed consent form to keep.

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This informed consent form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.



If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted for Lupin Research Inc. (Lupin). Your study doctor is being paid by Lupin to conduct this study.

Taking part in this study is entirely voluntary.

Section 1. Purpose of the Research

You are being asked to participate in this research study because you may have a condition called bacterial vaginosis (BV), in which there is an abnormal vaginal discharge due to an overgrowth of bacteria not usually present in the vagina combined with a decrease in the number of bacteria that are normally present in the vagina.

The purpose of this research study is to test the safety and effectiveness of the oral granule drug, Solosec (a form of secnidazole), for the treatment of BV. Solosec was approved in the United States by the Food and Drug Administration (FDA) in 2017 for the treatment of BV in adult women ages 18 years and older. The use of Solosec in this study is investigational. An investigational use is one that is not approved by the FDA. Lupin would like to gather additional information for the treatment of Solosec in girls aged 12-17 years old diagnosed with BV.

Solosec is an antibiotic of oral granules (small grains or particles) given by mouth. If you decide to participate in this study, you will be evaluated and examined to determine if you meet the requirements for study participation. If you are determined to be eligible, you will be entered into the study. You will then be given a single dose of active study drug (SYM-1219-401) to be mixed with about 4 ounces of unsweetened applesauce. The applesauce mixture will then be taken orally (by mouth) followed by 8 ounces of water.

Because this is a research study, the study drug will be given to you free of charge, only during this study. If the study doctor feels that you still need treatment after the study is over, you will then be offered an FDA-approved medication for treating your condition. The cost for this additional treatment will be paid by Lupin.

Approximately 40 subjects will be enrolled into this study.

Section 2. Procedures

You will be scheduled to visit the clinic two times during the study (Baseline Visit [Day 1] and Test of Cure /End of Study [TOC/EOS] Visit on Day 7-14). A follow up telephone interview will be performed between Day 21-30.



Section 3. Time Duration of the Procedures and Study

Baseline Visit (Study Visit Day 1)

The following procedures will be completed prior to being given any study treatment:

1. Prior to any study-specific procedures are performed, this informed consent form will be reviewed with you by a site staff member. You will be asked to initial the bottom of each page and sign and date the last page of the form. The Authorization for Use or Disclosure of Health Information Form will also be reviewed with you and you will be asked to sign and date that form, as well as the authorization to use and disclose medical information. A copy of the signed and dated forms will be provided to you for your records.
2. Demographic information including date of birth, sex, race, and ethnicity will be collected from you;
3. Your medical history will be collected;
4. Your BV history and prior treatments will be collected;
5. Your prior and concomitant medication (other medicines you are currently taking) use will be collected;
6. Urine will be collected for a urine pregnancy test;
7. You will have a physical exam, including vital signs (blood pressure and pulse), weight and height;
8. You will have a pelvic examination, and vaginal samples will be collected to determine if you have any of the following:
 - a. Bacterial vaginosis
 - b. Other vaginal condition(s), such as a yeast infection, and, if so, you are not eligible for the study.
 - c. Sexually transmitted infections (STIs), such as gonorrhea, trichomonas and/or chlamydia. These test results may not be available at this Baseline Visit. You will be allowed to enroll into the study and receive study drug before these test results are made available to the study staff. However, you will be notified if you have any STI for which you were tested and will be asked to return to the study site for an End of Study (EOS) Visit as soon as possible. **Note that positive STI test results may be reportable to local health authorities according to local laws.**
9. You will have to give blood (approximately 2 teaspoons) and urine samples for safety laboratory tests;
10. You will need to meet all the study requirements that will be reviewed with you by the study staff.

If you meet all of the study requirements, including the test results that are available at your Baseline Visit (Study Day 1), the following will be done:

You will receive the following study treatment:



1. SYM-1219 (a granule formulation containing 2 grams of secnidazole) as a single oral dose.
2. You will be provided with the study drug and dosing instructions. You will be asked to follow the dosing instructions to prepare and take the single dose of study drug. After you take the study drug, you will drink approximately 8 ounces of water.
3. The study staff will schedule a Test of Cure (TOC) / End of Study (EOS) clinic Visit with you between Study Days 7-14.

Test of Cure Visit (Study Day 7-14) / End of Study (EOS) Visit

You will return to the clinic for the TOC / EOS Visit between Study Day 7 and 14.

If it is determined that you did not meet all of the study eligibility criteria, or in the opinion of the study doctor you should not continue in this study, or if you decide you want to discontinue your participation in the study before Study Day 7, you may be asked to return to the clinic earlier than Day 7.

You should not be on your period during this visit. If you are on your period (or expect to be on your period) on the date of this visit, you should call the study staff to reschedule the visit.

The following procedures will be performed at the TOC/EOS Visit:

1. You will be asked about any bad side effects that you have experienced;
2. Your concomitant medications/treatments taken during the study will be reviewed with you and recorded;
3. A urine sample will be collected for a urine pregnancy test;
4. You will have a physical examination as needed to assess adverse events
5. Your vital signs (blood pressure and pulse) will be collected;
6. You will have a pelvic examination, and vaginal samples will be collected;
7. Blood (approximately 2 teaspoons) and urine samples will be collected for analysis at the central laboratory;
8. The study doctor will make an assessment for the need of additional treatment for BV.

Subject Telephone Interview (Study Day 21-30)

You will be called by clinic staff between Study Day 21 and 30 and you will be asked about any new or changes to adverse events and concomitant medications and/or you will be asked the following questions:

The following information will be collected:

1. Assess for adverse events;
2. Review and record concomitant medications/treatments.
3. Conduct telephone interview.



EXPECTATIONS

If you participate in this study, you will be expected to do the following:

- Follow the instructions that you are given;
- Tell the study doctor or study staff about any changes in your health;
- Tell the study doctor or study staff if you want to stop being in the study at any time;
- If you are using birth control, you must continue to use the same birth control method during the study. If you change your birth control, or you feel that you may be pregnant, you will need to tell the study doctor as soon as possible;
- You must not have any vaginal penetration or use of any vaginal products until after the TOC visit (for example, spermicides, condoms, diaphragms, vibrators, tampons, etc.)
- You must not use vaginal douches or similar products for the duration of the study;
- You must come to the study center when required by your study doctor.

Section 4. Discomforts and Risks

The most common known side effects observed in previous studies with Secnidazole are the following:

- Headache
- Abdominal pain
- Nausea
- Diarrhea
- Metallic taste
- Vaginal yeast infections
- Vulvovaginal pruritus (itching)
- Vomiting

Secnidazole, the active ingredient in SYM-1219, has been approved and used in Europe, Asia and South America for over twenty (20) years for a variety of different infections as both single dose and multiple dose treatments.

In addition to the side effects noted above, other common side effects reported for secnidazole include the following:

- Abdominal pain
- Vomiting
- Diarrhea
- Constipation
- Loss of appetite
- Swollen patches on the tongue
- Inflammation or redness of the mouth

Blood draw:



Blood samples will be collected for blood counts, your kidney and liver function, and to measure the levels of minerals and sugar levels in your blood. Your samples will not be labeled with your name, they will be labeled with a subject ID number, gender, and year of birth. Your samples will be sent off site for processing. Anyone who works with your samples will hold the information and results in confidence. After analysis (tests) for the study is complete, your samples will be destroyed. If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.

The area of the skin will be wiped with alcohol before placing a needle in the vein and a small blood sample is drawn. The laboratory blood tests will require approximately 5.5 mL of your blood to be drawn. Although one blood draw is usually sufficient, a second one may be necessary if the first is not successful.

There may be side effects of having blood drawn such as:

- Fainting
- Dizziness
- Pain
- Bruising, swelling, or redness at blood draw site
- Bleeding
- Small risk of infection
- Scarring at the site of the needle stick

If you feel faint tell the study staff right away.

Pelvic Examinations:

Pelvic examination and procedures may cause mild discomfort or pressure in your vagina or pelvis. You may also have vaginal bleeding or spotting.

Routine Urine Tests:

At your baseline visit and Test of Cure/ End of study visit, you will be asked to provide a small sample of urine for testing. Your samples will be used to test for pregnancy (females only), your kidney function and to check the levels of minerals and sugar in your urine (urinalysis). Your samples will not be labeled with your name, they will be labeled with a subject ID number, gender, and year of birth. Some of your samples will be sent off site for processing and some will be processed at the site. After analysis for the study is complete, your samples will be destroyed. If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.



All drugs can have side effects or affect another drug that you are taking. Therefore, the use of the study drugs may involve risks to you that are presently unforeseen and unknown.

During the study, your bacterial vaginosis may become worse, stay the same, or improve.

Allergic Reaction Risks:

You cannot enter this study if you are allergic or hypersensitive to Solosec, and it is contraindicated in patients who have shown hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives, or known hypersensitivity to any of the proposed ingredients or components of the delivery system.

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Fast pulse
- Sweating
- A feeling of dread
- Hives
- Itching
- Tingling and swelling of the eyes, face, lips, tongue, throat and/or vocal cords
- Difficulty breathing
- Inability to breathe without assistance
- Wheezing
- A sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Seizures (convulsions)
- Loss of consciousness
- Possibly death

UNFORESEEN RISKS:

Since the study drug (SYM-1219) is investigational, when taken alone or in combination with other medications, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

Please seek treatment immediately and tell the study doctor and study staff if you have any of the symptoms listed above, or any other side effects, during the study.

PREGNANCY / BIRTH CONTROL:

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be



pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks the embryo, fetus, or nursing baby that are not known at this time.

In order to reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable during this study. The use of NuvaRing® or any other vaginal ring products are not allowed.

It is important for you to tell the study doctor at once if you get pregnant or think that you might be pregnant while you are in the research study. If you get pregnant, you will be asked to stop taking part in the study. You may also be asked questions about your pregnancy and the baby. The study doctor may share this information with the Sponsor.

Payment for all aspects of obstetrical care, child-or related care, will be your responsibility.

Section 5. Potential Benefits

You may benefit as a result of your participation in this study where your symptoms of BV may improve. There is; however, no guarantee that you will benefit from your participation in this study. Results from this study may benefit others in the future.

Section 6. Statements of Confidentiality and Privacy

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Section 7. Compensation for Injury

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

If you become ill or are hurt directly because of this drug (Secnidazole) or procedures described in this informed consent form, you will be paid back for your out-of-pocket (not paid by



insurance or someone else) costs for reasonable standard medical expenses. In order for you to be paid back, you must tell the study doctor of your illness/injury as soon as possible, and follow the directions of the study doctor and staff and this informed consent form. If it is determined that you did not follow the protocol or other study instructions, you may not be paid back for such costs. You will not be paid back for treatment of illnesses or injuries that you had before you started the study, unless the study drug or procedure worsened your previous illness or injury. In order to receive payment, you should keep a record of all of your expenses, including where and when you received treatment for your illness or injury. The offer to provide the payment described above does not mean that the illness or injury is the fault of the Lupin or the study doctor/facility. Compensation for injuries will not be provided beyond that specified above.

You will not lose any of your legal rights by signing this document.

Section 8. Compensation for Participation

You will be paid up to a total of \$xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- \$xx.xx for Visits xxx.
- \$xx.xx for Visits xxx.
- \$xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ **'after each visit', 'annually', 'bi-weekly', etc.**

If you have any questions regarding your compensation for participation, please contact the study staff.

OR

You will not receive any monetary compensation for your participation in this study.

If applicable: We will reimburse you for the cost of **[describe: e.g., traveling to your study visits]**. You will be reimbursed approximately **[e.g., 2 weeks, one month, etc.]** after you submit your travel receipts to the study staff.



Section 9. Voluntary Participation

Your decision to participate in this study is voluntary. You may choose not to participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

If you decide to withdraw from the study early for any reason, you will be asked to return for the following procedures:

- You will be asked by the staff about any adverse events;
- You will be asked about any medications that you have taken during the study;
- You will have a urine pregnancy test;
- You will have a physical examination, including vital signs;
- You may have a pelvic examination, and vaginal samples may be collected;
- You will have to give blood (approximately 5.5 teaspoons) and urine samples for safety laboratory tests;
- You will meet with a study doctor to determine if you need additional treatment for your condition.

You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your study doctor may solely decide to take you out of the research study. Some possible reasons for this are:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons, including competitive enrollment - the target number of subjects has entered the study.

Also, Lupin may end the research study early. If your participation in the study ends early, you may be asked to visit the study doctor for a follow up and/or a final visit.

You are not to participate in another clinical trial while in this research, you should discuss the procedures and/or treatments with your physician and/or the study doctor. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.



During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 10. Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00029604.

Section 11. Other Alternatives to Entering This Study

You do not have to be in this study to receive treatment for your BV. There are marketed treatments available to help people with BV. Your options may include treatments like the following:

- Metronidazole (Flagyl®), as a pill
- Metronidazole (Metrogel®), as a vaginal gel or
- Clindamycin (Clindesse®), as a vaginal cream



Section 12. Procedures for Termination of Study Participation

You can be removed from the study at any time and for any reason without your consent. Some of the reasons you can be removed are listed below.

- You do not follow the instructions, rules, and restrictions given by the study staff.
- You do not continue to meet the requirements for the study.
- The Study Doctor decides it is best for your health.
- The Sponsor stops the study or asks that you be removed from the study.
- You become pregnant.



Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with the study doctor,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature and date below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant’s Parent or Legal Guardian: By signing and dating below, you indicate that you give permission for the participant to take part in this research.

_____	_____	_____	_____
Signature of Parent or Legal Guardian	Date	Time	Printed Name of Parent or Legal Guardian

Person Explaining the Research Study: Your signature and date below means that you have explained the study research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research study	Date	Time	Printed Name

If the study requires the use of an assent document, please follow the directions of the specific Institutional Review Board or Ethics Committee for their requirements for this document. This is necessary as there are regional specifications involved.
Based on local requirement, each site should obtain documented proof or evidence of child custody.

FOR PARENTS/LEGAL GUARDIANS WHO CANNOT READ

The study parent/legal guardian has indicated that he/she is unable to read. The consent document has been read to the parent/legal guardian by a member of the study staff, discussed with the parent/legal guardian by a member of the study staff, and the parent/legal guardian has been given an opportunity to ask questions of the study



Printed Name of Impartial Witness

Signature of Impartial Witness*

Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject’s legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject.

STATEMENT OF ASSENT FOR AGES 12 – 17

I have read this form. I know that this is a research study. I have been told about the risks and potential benefits of taking part in the study. I have asked all the questions I have about the study and have gotten answers to my questions. I know that I am free to quit the study at any time without any penalties or loss of benefits. I will tell the study doctor, the study staff or my parent(s)/guardian(s), if I choose to stop the study. I will be given a signed and dated copy of this form to keep.

I agree to take part in this research study.

Printed Name of Child Participant

Child Assent Signature

Date

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all of the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject’s decision to enroll is voluntary.
5. The study doctor and study staff agrees to respect the subject’s physical or emotional dissent at any time during this research study.

Signature of Person Conducting Assent Discussion

Date

Time

Printed Name



AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include

- Representatives of Lupin.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:



- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Printed Name of Subject



Printed Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian

Date

Printed Name of the Person Obtaining the
Authorization

Signature of the Person Obtaining the
Authorization

Date

WITNESS SIGNATURE FOR PARENTS OR LEGAL GUARDIANS WHO CANNOT READ

The subject's parent/legal guardian has indicated that he/she is unable to read. This Authorization document has been read to the subject's parent or legal guardian by a member of the study staff, discussed with the subject's parent or legal guardian by a member of the study staff, and the subject's parent or legal guardian has been given an opportunity to ask questions of the study staff.

Printed Name of Impartial Witness

Signature of Impartial Witness

Date